

## **DETAILED ACTION**

### ***Preliminary Remark***

1. Applicant's submission on February 11, 2009 is acknowledged. Claims 1-47 are currently pending. Claim 46 has been amended.

The non-final Office Action mailed on February 3, 2009 inadvertently cited Chen in section 1. Accordingly, the non-final Office Action mailed on February 3, 2009 is **VACATED**. This non-final Office Action is responsive to Applicant's submissions filed on November 12, 2008 and February 11, 2009.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group II, claims 20-39, 46, and 47 in the reply filed on November 12, 2008 is acknowledged. The traversal is on the ground(s) that the prior art of Van Beuningen, which was cited in the restriction requirement, does not teach all of the limitations of the instant claim 1, and therefore, the claims possess a special technical feature linking them over the prior art (see pages 2-3). In particular, Applicant argues that the Van Beuningen reference does not teach the limitations appearing in lines 8-10 of claim 1 (see pages 2-3). Applicant's arguments were not persuasive, because lines 8-10 of claim 1 constitute a statement of an intended use, and therefore, do not further limit the positively recited method steps appearing in lines 1-7 of the claim. At most lines 8-10 of claim 1 require that the control nucleic acid is capable of being desorbed from the solid support. Since Van Beuningen teaches non-covalent adsorption of control nucleic acids on the solid support (page 15, lines 18-23), the control nucleic acids of Van Beuningen are inherently capable of being desorbed from the solid

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support in a definite amount. Thus, Van Beuningen teaches all of the elements of claim 1, and as a result, the claims lack a special technical feature linking them over the prior art. Accordingly, a lack of unity requirement is proper.

Furthermore, it is noted that the claims lack a special technical feature linking them over the prior art, because the prior art of Grosch et al. (EP 0 133 288 A2) and Mullenix et al. (US 2003/0175740 A1; cited on an IDS) teach all of the limitations of the instant claims 20-25, 27-30, 32, and 34-36 (see below). Since the claims lack a special technical feature linking them over the prior art, a lack of unity requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-19 and 40-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 12, 2008.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

4. Applicant's submission of an Information Disclosure Statement on December 9, 2008 and on June 21, 2006 is acknowledged. Signed copies are enclosed.

***Drawings***

5. The drawings filed on June 21, 2006 are acceptable.

***Claim Objections***

6. Claims 46 and 47 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 46 and 47 have not been further treated on the merits.

Claims 20-39 are objected to because of the following informalities: These claims depend from a withdrawn claim – claim 1.

Claims 20-39 are also objected to because of the following informalities: These claims contain grammatical and/or typographical errors. The following changes are suggested:

- (i) Insertion of the word “A” at the beginning of claims 20-39;
- (ii) Insertion of the conjunction “and” in claim 20 at the end of line 16;
- (iii) Replacement of the word “promoting” in claim 20 with "promotes";
- (iv) Deletion of what appears to be a duplicate recitation of "nucleic acid originating from” in line 3 of claim 22;

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(v) Correction of the grammatically incorrect phrase “any naturally occurring agent being pathogen to a mammalian, especially to human” appearing in claim 22;

(vi) Deletion of the extra spaces appearing in claim 23;

(vii) Insertion of the word “of” after the phrase “in the range” appearing in claims 31, 33, and 37-39; and

(viii) Correction of the grammatically incorrect recitation “said series of supports provides with a” in lines 4-5 of claim 39.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 20-39, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether

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the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, independent claim 20 recites the broad recitation “promoting the stability of the control nucleic acid on said solid support” in lines 14-15, and the claim also recites “especially in the course of storage” in line 15, which is the narrower statement of the range/limitation.

Claims 20-39 are further indefinite, because independent claim 20 recites “wherein said carrier agent is selected from the group of albumins” in lines 18-19. The phrase “selected from the group” implies the presence of more than one member, but the claim only recites one member of the group - albumins. As a result, it is unclear whether other carrier agents are intended to be encompassed in the group of carrier agents or if the above recitation is the result of a grammatical issue, and a recitation such as “wherein said carrier agent is an albumin” was intended.

Further regarding claims 22, 24, 26, 31, 33, and 37-39, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

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remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 22 recites the broad recitation “wherein said carrier agent is a nucleic acid unrelated to any nucleic acid originating from nucleic acid originating from any naturally occurring agent being pathogen to a mammalian” in lines 2-3, and the claim also recites “especially to human” in line 4, which is the narrower statement of the range/limitation.

Likewise, claim 24 recites the broad recitations “herring DNA” and “salmon DNA” in line 5, and the claim also recites “especially herring sperm DNA” in line 4 and “salmon sperm DNA” in lines 4-5, which are narrower statements of these ranges/limitations. Also, claim 26 recites the broad recitations “0.1 – 50 µg of nucleic acids” and “2 - 100 µg of albumin”, and the claim also recites “preferably 1-10 µg”, “more preferably 4-8 µg”, “even more preferably 5-6 µg”, “preferably 5-50 µg”, “more preferably 10-30 µg”, and “even more preferably 15-20 µg”, which are narrower statements of these ranges/limitations. Also, claim 31 recites the broad recitation “a thickness in the range 50-3000 microns” in line 2, and the claim also recites “preferably 100-1500 microns” and “more preferably 150-1000 microns” in line 3, which are narrower statements of the range/limitation. Also, claim 33 recites the broad recitation “a surface in the range 10-500 mm<sup>2</sup>” in line 2, and the claim also recites “preferably 20-250 mm<sup>2</sup>” and “more preferably 30-200 mm<sup>2</sup>” in line 3, which are narrower statements of the range/limitation. Also, claim 37 recites the broad recitation “an amount in the range 10 – 10<sup>8</sup> copies” in line 3, and the claim also recites “10<sup>2</sup> – 10<sup>5</sup> copies” in line 3, which is a narrower statement of the range/limitation. Also, claim 38 recites the broad recitation “an amount in the range 10-1000 copies” in line 3, and the claim also

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recites "preferably 20-500 copies" and "more preferably 50-100 copies" in line 3, which are narrower statements of the range/limitation. Also, claim 39 recites the broad recitation "a calibration range of said control nucleic acid", and the claim also recites "preferably in the range  $10 - 10^8$  copies", "more preferably  $10^2 - 10^5$  copies", "even more preferably 20-500 copies", and "most preferably 50-100 copies", which are narrower statements of the range/limitation.

Claims 23-25 are further indefinite, because they recite Markush groups that do not contain the conjunction "and" prior to recitation of the last member of the group. As a result, the scope of these claims is unclear.

Further regarding claims 24 and 25, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Further regarding claim 26, the phrase "for example" in line 5 renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Further regarding claim 26, it is unclear as to what amounts of nucleic acid and albumin are required, since the concentration units (*e.g.* micrograms or milligrams) are replaced by boxes. For examination purposes, the amounts have been considered to be micrograms, since micrograms were recited in the previous version of this claim.

Claims 28-30 are indefinite, because they recite the limitation "said membrane material" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is sufficient antecedent basis for "said membrane".

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Claim 34 is further indefinite, because the recitation “including DNase and/or RNase activity” appearing in claim 34 is exemplary claim language that renders the scope of the claim unclear. See MPEP 2173.05(d).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 20-25, 27-30, 32, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Grosch et al. (EP 0 133 288 A2).

Claims 20-25, 27-30, 32, and 34-36 are drawn to solid supports upon which a carrier agent and a control nucleic acid is adsorbed.

Regarding claims 20, 34, and 35, Grosch teaches a solid support comprising an absorbent support that permits non-covalent adsorption of control nucleic acids and that is heat-treated to be essentially devoid of enzymatic activity (see page 39, lines 7-30, where the nitrocellulose membrane is taught). It is noted that the heating step taught by Grosch at page 39, lines 21-30 results in the support being essentially devoid of enzymatic (*e.g.* nuclease) activity. The solid support of Grosch further comprises two carrier agents, specifically bovine serum albumin (BSA) and salmon sperm DNA, adsorbed thereupon (see page 39, lines 21-30). The salmon sperm DNA is a nucleic acid unrelated to the control nucleic acid (*i.e.* nucleic acids isolated from mammalian cells – see page 39, lines 14-20) and the target nucleic acid (*i.e.* nucleic acids



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isolated from bacterial cells – see page 38, line 7 – page 39, line 13). The solid supports also comprise a control nucleic acid adsorbed thereupon (see page 39, lines 14-20, where the mammalian cell nucleic acids are immobilized on the nitrocellulose membrane).

Further regarding claim 20, it is noted that the preamble of the claim only recites an intended use for the solid supports and does not further limit the structural features of the claimed solid supports. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is also noted that the recitations present in lines 11-15 of claim 20 are statements of intended use. Recitations of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the intended use recitations appearing in lines 11-15 of claim 20 do not further limit the structure of the claimed solid supports. Since Grosch teaches solid supports having all of the claimed features, claims 20, 34, and 35 are anticipated by the prior art of Grosch.

Regarding claims 21 and 22, the carrier agent (salmon sperm DNA) taught by Grosch is a nucleic acid unrelated to any naturally occurring human nucleic acid. The salmon sperm DNA taught by Grosch also is not a nucleic acid originating from an organism that is pathogenic to mammals, such as humans.

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Regarding claims 23-25, Grosch teaches that the carrier agents are bovine serum albumin (BSA) and salmon sperm DNA (page 39, lines 21-30).

Regarding claims 27-30, Grosch teaches that the solid support is a nitrocellulose membrane, which is a cellulose-derived material (page 39, lines 7-30).

Regarding claim 32, Grosch teaches that the solid support has a square shape (page 40, lines 7-20).

Regarding claim 36, the control nucleic acids of Grosch (*i.e.* the nucleic acids isolated from mammalian cells – see page 39, lines 14-20) are a negative control (see Table B on page 41).

10. Claims 20-25, 27-30, 32, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullenix et al. (US 2003/0175740 A1; cited on an IDS).

Claims 20-25, 27-30, 32, and 34-36 are drawn to solid supports upon which a carrier agent and a control nucleic acid is adsorbed.

Regarding claims 20, 34, and 35, Mullenix teaches a solid support comprising an absorbent support that permits non-covalent adsorption of control nucleic acids (see paragraph 244; see also paragraphs 156 and 160-169, where Mullenix teaches alternative solid supports). It is noted that the hybridization reactions taught in paragraphs 246-249 are inherently conducted at temperatures at which enzymes, such as nucleases, are inactivated. Therefore, the solid support of Mullenix has been or is treated with heat to essentially inactivate nucleases as required by claims 20 and 34. The solid support of Mullenix further comprise at least one carrier agent, specifically salmon sperm DNA or polyA, adsorbed thereupon (paragraphs 244 and 247). The

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salmon sperm DNA is a nucleic acid unrelated to the control nucleic acid (*i.e.* the control DNA PCR products – see paragraphs 228, 244, and 247) and the target nucleic acid (*i.e.* the fluorescently labeled HeLa cDNA - see paragraphs, 243, 244, and 247). The solid supports also comprise a control nucleic acid adsorbed thereupon (see paragraph 244, where the control DNA PCR products are taught).

Further regarding claim 20, it is noted that the preamble of the claim only recites an intended use for the solid supports and does not further limit the structural features of the claimed solid supports. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is also noted that the recitations present in lines 11-15 of claim 20 are statements of intended use. Recitations of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the intended use recitations appearing in lines 11-15 of claim 20 do not further limit the structure of the claimed solid supports. Since Mullenix teaches solid supports having all of the claimed features, claims 20, 34, and 35 are anticipated by the prior art of Mullenix.

Regarding claims 21 and 22, the carrier agent (salmon sperm DNA) taught by Mullenix is a nucleic acid unrelated to any naturally occurring human nucleic acid. The salmon sperm DNA

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taught by Mullenix also is not a nucleic acid originating from an organism that is pathogenic to mammals, such as humans.

Regarding claims 23-25, Mullenix teaches that the carrier agents are polydA and salmon sperm DNA (paragraph 244).

Regarding claims 27-30, Mullenix teaches that the solid support is a nitrocellulose membrane, a nylon membrane, or a cellulose membrane (paragraphs 160-166).

Regarding claim 32, Mullenix teaches that the solid support has a disc or square shape (paragraph 161).

Regarding claim 36, the control nucleic acids of Mullenix (*i.e.* the control DNA PCR products) are a positive control (paragraphs 244 and 247). Mullenix also teaches immobilizing negative controls, qualitative controls, semi-quantitative controls, and quantitative controls on the solid support (paragraphs 191-209).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 26, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grosch et al. (EP 0 133 288 A2).

Claim 26 is drawn to the solid support of claim 20, wherein the carrier agent comprises a particular amount of nucleic acids or albumin. Claims 37 and 38 are drawn to the solid support of claim 35, wherein a particular concentration of the control nucleic acid is adsorbed on the solid support.

Grosch teaches the solid supports of claims 20-25, 27-30, 32, and 34-36, as discussed above.

Grosch teaches concentrations of carrier agents (BSA and salmon sperm DNA) that lie outside the claimed concentration ranges (see page 39, lines 21-30). Grosch also does not specify the amount of control nucleic acids adsorbed on the solid support as required by claims 37 and 38.

However, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to optimize the results-effective variables using routine experimentation. An ordinary artisan would have been motivated to optimize the concentration of carrier agent immobilized on the solid support in order to determine the minimal concentration of carrier agent capable of providing the desired effect (*e.g.* blocking non-specific adsorption of proteins or nucleic acids), thereby conserving reagents and minimizing waste. An ordinary artisan also

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would have been motivated to optimize the concentration of immobilized nucleic acids on the solid support in order to obtain optimal hybridization results. Attention is also directed to MPEP 2144.05, which states, “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. ‘[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.’ *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).” In this case, no evidence has been suggested to suggest that the selection of the claimed concentrations of carrier agent or immobilized control nucleic acid was other than routine or that the results should be considered unexpected in any way relative to the prior art of Grosch. Accordingly, the solid supports of claims 26, 37, and 38 are *prima facie* obvious over Grosch in the absence of secondary considerations.

13. Claims 26, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullenix et al. (US 2003/0175740 A1; cited on an IDS).

Claim 26 is drawn to the solid support of claim 20, wherein the carrier agent comprises a particular amount of nucleic acids or albumin. Claims 37 and 38 are drawn to the solid support of claim 35, wherein a particular concentration of the control nucleic acid is adsorbed on the solid support.

Mullenix teaches the solid supports of claims 20-25, 27-30, 32, and 34-36, as discussed above.

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Mullenix does not teach that the concentration of the carrier agents (polydA and salmon sperm DNA) lie within the claimed concentration range. Mullenix also does not teach that the control nucleic acids are adsorbed on the solid support at a concentration within the ranges recited in claims 37 and 38.

However, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to optimize the results-effective variables using routine experimentation. An ordinary artisan would have been motivated to optimize the concentration of carrier agent immobilized on the solid support in order to determine the minimal concentration of carrier agent capable of providing the desired effect (*e.g.* blocking non-specific adsorption of nucleic acids), thereby conserving reagents and minimizing waste. An ordinary artisan also would have been motivated to optimize the concentration of immobilized nucleic acids on the solid support in order to obtain optimal hybridization results. Attention is also directed to MPEP 2144.05, which states, “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. ‘[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.’ *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).” In this case, no evidence has been suggested to suggest that the selection of the claimed concentrations of carrier agent or immobilized control nucleic acid was other than routine or that the results should be considered unexpected in any way relative to the prior art of Mullenix. Accordingly, the solid supports of claims 26, 37, and 38 are *prima facie* obvious over Mullenix in the absence of secondary considerations.

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14. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grosch et al. (EP 0 133 288 A2) or Mullenix et al. (US 2003/0175740 A1; cited on an IDS) in view of Johnson (US 5,411,663).

Claim 31 is drawn to the solid support of claim 27, wherein the membrane has a thickness between 50-3000 microns.

Grosch and Mullenix separately teach the solid supports of claims 20-25, 27-30, 32, and 34-36, as discussed above.

Neither Grosch nor Mullenix specifies the thickness of the nitrocellulose solid supports.

Johnson teaches a solid support, specifically a membrane, for conducting nucleic acid hybridization (see Example 1 at column 7, lines 27-63). The membrane taught by Johnson has a thickness of 120 microns (column 7, lines 53-54), which lies within the claimed range of 50-3000 microns.

It would have been *prima facie* obvious to substitute the membrane of Johnson for the nitrocellulose membranes taught by Grosch or Mullenix. An ordinary artisan would have been motivated to substitute any membrane known to be suitable for use in nucleic acid hybridization methods as the solid support of Grosch or Mullenix recognizing its suitability for the intended purpose. As noted in MPEP 2144.06, it is *prima facie* obvious to substitute art-recognized equivalents known to be useful for the same purpose in the absence of secondary considerations. Also, as noted in MPEP 2144.07, it is *prima facie* obvious to select a known material based on its suitability for the intended purpose. In this case, the prior art of Johnson taught that a membrane having a thickness within the claimed range was suitable for use in a hybridization method (see Example 1 at column 7, lines 27-63). Thus, an ordinary artisan would have been



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motivated to substitute the membrane of Johnson for the nitrocellulose membrane taught by either Grosch or Mullenix with a reasonable expectation of success. Thus, the solid support of claim 31 is *prima facie* obvious over Grosch in view of Johnson or Mullenix in view of Johnson.

15. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grosch et al. (EP 0 133 288 A2) or Mullenix et al. (US 2003/0175740 A1; cited on an IDS) in view of Saxinger et al. (Proceedings of the National Academy of Sciences, USA (1972) 69(10): 2975-2978).

Claim 33 is drawn to the solid support of claim 27, wherein the membrane has a surface in the range of 10-500 mm<sup>2</sup>.

Grosch and Mullenix separately teach the solid supports of claims 20-25, 27-30, 32, and 34-36, as discussed above.

Grosch teaches membranes with a surface area of approximately 13548 mm<sup>2</sup>, which lies outside the claimed range. Mullenix does not specify the surface area of the membrane solid supports.

Saxinger teaches cellulose-derived filters for conducting nucleic acid hybridization reactions (see page 2975). The filters of Saxinger have a diameter of 7 mm (page 2975, column 2), which results in a surface area of approximately 38 mm<sup>2</sup>. This surface area lies within the claimed range.

It would have been *prima facie* obvious to substitute the membrane of Saxinger for the nitrocellulose membrane taught by Grosch or Mullenix. An ordinary artisan would have been motivated to substitute any membrane known to be suitable for use in nucleic acid hybridization methods as the solid support of Grosch or Mullenix recognizing its suitability for the intended

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purpose. As noted in MPEP 2144.06, it is *prima facie* obvious to substitute art-recognized equivalents known to be useful for the same purpose in the absence of secondary considerations. Also, as noted in MPEP 2144.07, it is *prima facie* obvious to select a known material based on its suitability for the intended purpose. In this case, the prior art of Saxinger taught that a membrane having a surface area within the claimed range was suitable for use in a hybridization method (see page 2975). Thus, an ordinary artisan would have been motivated to substitute the membrane of Saxinger for the nitrocellulose membrane taught by Grosch or Mullenix with a reasonable expectation of success. Thus, the solid support of claim 33 is *prima facie* obvious over Grosch in view of Saxinger or Mullenix in view of Saxinger.

16. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullenix et al. (US 2003/0175740 A1; cited on an IDS) in view of Sabanayagam et al. (Nucleic Acids Research (2000) 28(8): e33).

Claim 39 is drawn to a series of solid supports that comprise a plurality of solid supports according to claim 35, wherein each of the solid supports carries a different standardized amount of the same control nucleic acid adsorbed thereupon, such that the series of supports provides a calibration range of the control nucleic acid.

Mullenix teaches the solid supports of claims 20-25, 27-30, 32, and 34-36, as discussed above.

Mullenix does not teach a series of supports each having a different standardized amount of the control nucleic acid immobilized thereupon as required by claim 39.

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Sabanayagam teaches arrays of immobilized oligonucleotides (see abstract and page i). Sabanayagam teaches that several different concentrations of the same oligonucleotide were immobilized on the array to determine the binding capacity of the oligonucleotide probe (see pages ii-iii and Figure 3).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to combine the teachings of Mullenix and Sabanayagam. An ordinary artisan would have been motivated to generate a series of solid supports (*e.g.* beads, as taught by Mullenix at paragraphs 161 and 167) each having a different concentration of the same control nucleic acid adsorbed thereupon, since Sabanayagam taught that immobilization of different concentrations of the same oligonucleotide permitted determination of the binding capacity of the oligonucleotide probe (see pages ii-iii and Figure 3). Thus, the solid supports of claim 39 are *prima facie* obvious over Mullenix in view of Sabanayagam.

### ***Conclusion***

17. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/GARY BENZION/

Supervisory Patent Examiner, Art Unit 1637